IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO ETHICON WAVE 5 CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

REPLY BRIEF IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE CERTAIN GENERAL OPINIONS OF BRUCE ROSENZWEIG, M.D.

Defendants Ethicon, Inc. and Johnson & Johnson (hereinafter "Ethicon") submit this reply brief in further support of their motion to exclude certain opinions of Bruce Rosenzweig, M.D.

I. Plaintiffs' broad and vague attempts to rely on unspecified prior reports of Dr. Rosenzweig are improper.

Just because Ethicon did not cite a rule or court order does not mean that Plaintiffs should be allowed to continue to designate numerous expert reports of Dr. Rosenzweig. Ethicon filed a motion about this very issue, and Plaintiffs failed to respond. *See* Doc. 4045. At this point in the litigation, the number of Dr. Rosenzweig's reports is becoming unwieldy, and to make matters worse, he is even attempting to incorporate by reference other experts' reports. If, as Plaintiffs state, Dr. Rosenzweig's new reports "clearly reveal the opinions he intends to give at trial," there is no reason for Plaintiffs and Dr. Rosenzweig to make vague references to other "past reports." It is only fair that Plaintiffs identify one report per device so that Ethicon may have certainty about the opinions that Dr. Rosenzweig intends to offer and to alleviate any potential confusion.

II. The Court should preclude Dr. Rosenzweig from testifying that non-synthetic mesh procedures are a safer alternative.

Plaintiffs correctly note that, in prior waves, this Court stated that it would consider Ethicon's challenges to Dr. Elliott's opinions about non-synthetic mesh procedures on a "case-by-case basis." *See In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4500766, at *4 (S.D.W. Va. Aug. 26, 2016). Plaintiffs, however, fail to acknowledge that, since that time, this Court has: (a) found that such challenges should not be raised in case-specific motions, *Brooks v. Ethicon, Inc.*, No. 2:12-cv-02865, Mem. Op. at 4 (S.D.W. Va. July 12, 2017) (Ex. K to Doc. 4374); and (b) issued a blanket exclusion of such opinions from another expert pelvic surgeon (*In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2017 WL 1264620, at *3 (S.D.W. Va. Mar. 29, 2017)).

Regardless of which state's law applies, Dr. Rosenzweig—as with Dr. Goodyear—should never be allowed to suggest that traditional surgical procedures are safer alternatives to the devices at issue. These are medical device cases, not medical malpractice cases. Plaintiffs wish for the juries in these cases to conclude that a device can be found defective if the physician should have performed a different kind of surgery instead. But a device case is about devices, not surgeries. If there is no better way to make the device, then the choice of surgeries is up to the surgeon. *Theriot v. Danek Medical Inc*., 168 F.3d 253, 255 (5th Cir. 1999) (rejecting claim that pedicle screws were defective because a different surgery could have been performed: "The problem with this argument is that it really takes issue with the choice of treatment made by Theriot's physician, not with a specific fault of the pedicle screw sold by Danek").

The choice of a surgery or treatment is up to the surgeon. And here the implanting surgeons deliberately chose for their own reasons not to use the alternatives that Dr. Rosenzweig advocates.

Moreover, the fact that Ethicon has advocated surgery using the devices at issue as a more permanent alternative to traditional surgeries—which have their own unique complications, such as a high failure rate—does not make a comparison between the two the standard for deciding design defect. In the pedicle screw cases, Danek no doubt believed that pedicle screws were better than other surgical choices. A manufacturer is entitled to have opinions about medical procedures and to offer physicians a choice which juries should not be able to take away without evidence that the medical device could have been made in a safer way.

So if a plaintiff wants to invoke an alternative to impeach an existing "product," it necessarily must be another "product." Otherwise, the courts are comparing apples to oranges, not to other apples. For example, it is one thing to compare TVT to a similar minimally-invasive device with a low failure rate, but it is quite another to compare it to Burch colposuspension using no mesh but having a higher failure rate, especially when the success of either procedure will depend, among other things, on the experience and skill of implanting surgeon. That is a comparison for the surgeon to make, not the court.

This is a specialized application of a more general principle in product liability law that is not dependent on a state having a strict safer alternative design requirement. For example, in *Driesenstok v. Volkswagenwerk, A.C.*, 489 F. 2d 1066, 1074 (4th Cir. 1974), an unreasonable risk case, the court held that a Volkswagen bus could not be found to present an unreasonable risk just because it was less crashworthy than a sedan, because the two served their own "peculiar purposes." And in *Linegar v. Armour of Am. Inc.*, 909 F.2d 1150, 1154 (8th Cir. 1990), the court held that, for the purposes of an "unreasonably dangerous" claim under RESTATEMENT (SECOND) OF TORTS §402A, a bullet proof vest could not be faulted just because it

covered less than a bullet-proof jacket. Each served its own purposes although one alternative was manifestly safer than the other is some situations.

In a similar vein, the existence of an entirely different drug combination cannot make a drug defective even if they treat the same disease. *Brockert v. Wyeth Pharms., Inc*., 287 S.W.3d 760, 770-771 (Tex. App. – Houston 14th Dist. 2009). And on the other side is a case that endorses this same principle – alternatives must have the same "fundamental characteristic" – but found that a jury in a negligence case could find that to be true where the alternatives were either a lower dose or a natural version of the same drug. *Torkie-Tork v. Wyeth*, 739 F. Supp. 2d 895, 900 (E.D.W.Va. 2010). That is nothing like this case. As the Illinois federal district court said, distinguishing *Torkie-Tork*, here "the gap between the mesh product at issue here and a distinct surgical procedure is too large to merit submission to a jury." *Walker v. Ethicon, Inc.*, 2017 WL 2992301, at *3 n.3.

For these reasons, if a plaintiff wants to prove unreasonable danger by resorting to evidence of an alternative design, it has to be an alternative design of the same device, and not a different kind of device, and certainly not a different surgery, or treatment. Each of them serves its own "peculiar purposes," *Driesenstok, supra*, or has its own "fundamental characteristics." *Torrkie-Tork, supra*. It does not matter whether or not safer alternative design is a requirement in the jurisdiction. *See* Ex. A, Drug and Device Law Blog, "On Alternative Design, Take Two – Negligence" (Feb. 27, 2017) (discussing relevance of alternative design even absent statutory requirement). What matters is that the plaintiffs seek to prove their case by offering evidence of a safer alternative in order to prove liability, and what the liability is based on, whether it be unreasonable danger, negligence, or strict liability, does not matter.

The "peculiar purpose" of Ethicon's devices was to reduce the risk of surgical failure and to enable a particular kind of surgery. Traditional surgical procedures, such as native tissue surgery, do not serve either of those purposes and so cannot be considered a safer alternative for the purposes of product liability law. And given the vast numbers of patients successfully treated with Ethicon's products, there can be no claim—regardless of which state's law applies—that the product is so egregiously dangerous that it never should have been put on the market. *In re Alloderm(r) Litig.*, 2015 WL 5022618 (N.J. Super. L. Div. Aug. 14, 2015) (no egregious danger where hernia graft was admittedly useful in a subset of patients).

Finally, there is no merit to Plaintiffs' alternative argument that Coloplast Axis and other autologous slings should be considered a "product." Those slings are made from bodily tissue. In any event, even if they were a product and share the same general purpose, they are a completely different kind of product with their own unique advantages and disadvantages, and therefore, may not be compared as a safer alternative for the reasons set forth above. There is nothing that Ethicon could do to alter the design of its devices to make them more like autologous slings; it would need to stop manufacturing the devices altogether.

III. The Court should preclude Dr. Rosenzweig from testifying that devices with a different type of mesh are safer alternatives for the surgical treatment of SUI or prolapse.

Ethicon adopts its Wave 3 reply argument on this issue set forth in Section I of Doc. 3024.

IV. The Court should preclude Dr. Rosenzweig from criticizing the cut of TVT mesh.

Ethicon adopts its Wave 3 reply argument on this issue set forth in Section II of Doc. 3024.

V. The Court should limit Dr. Rosenzweig's product warning opinions.

Ethicon adopts its Wave 3 reply argument on this issue set forth in Section III of Doc. 3024.

VI. The Court should preclude Dr. Rosenzweig from testifying about alleged mesh degradation and other biomaterials opinions.

Ethicon adopts its Wave 3 reply argument on this issue set forth in Section IV of Doc. 3024.

VII. The Court should preclude Dr. Rosenzweig from testifying about duties allegedly owed by a manufacturer.

A. Testing

According to Plaintiffs, they "are not seeking reconsideration of" the Court's previous ruling excluding Dr. Rosenzweig from criticizing Ethicon's level of testing of the devices. Doc. 4374, Pl's Resp. at 11 (referencing *In re: Ethicon, Inc. Pelvic Mesh Prod. Liab. Litig.*, 2016 WL 4500765, at *5 (S.D.W. Va. Aug. 26, 2016)). Yet, in the next sentence, Plaintiffs ask the Court to "reconsider its prior ruling that Dr. Rosenzweig is not qualified to opine about Ethicon's testing." *Id.*

Aside from the self-contradictory nature of this assertion, Plaintiffs have not demonstrated that Dr. Elliott is competent to opine about what the standard of care supposedly required of a medical device manufacturer in terms of product testing and studies. The Court should reaffirm its prior ruling.

B. Adverse Event Reporting

Plaintiff have conceded that "Dr. Rosenzweig is not seeking to opine about the quality of Ethicon's adverse-event reporting." Doc. 4374, Pl's Resp. at 10.

C. Training

Plaintiffs' response does not address Ethicon's challenge to Dr. Rosenzweig's opinions about physician training, and therefore, the Court should exclude these opinions.

VIII. The Court should preclude Dr. Rosenzweig from testifying about certain alleged complications associated with TVT-Abbrevo.

Ethicon adopts its Wave 3 reply argument on this issue set forth in Section VI of Doc. 3024.

IX. The Court should exclude Dr. Rosenzweig's marketing opinions.

As noted by Plaintiffs, "[t]he Court has previously excluded Dr. Rosenzweig from opining about Defendants' marketing practices, and Plaintiffs are not seeking reconsideration of that ruling at this time." Doc. 4374, Pl's Resp. at 10.

X. The Court should preclude Dr. Rosenzweig from testifying about MSDS sheets.

Ethicon adopts its Wave 3 reply argument on this issue set forth in Section VIII of Doc. 3024.

XI. The Court should prevent Dr. Rosenzweig from providing general opinions about Prolift.

Ethicon does not object to Dr. Rosenzweig providing case-specific opinions about Prolift provided that those opinions were properly disclosed and Plaintiffs have not attempted to circumvent the Court's limitations on the number of general causation experts the parties may disclose. Based on Plaintiffs' representations in their response, Ethicon agrees that this is a matter than may be addressed on a case-by-case basis.

XII. The Court should not allow other opinions that are beyond Dr. Rosenzweig's expertise and/or otherwise improper.

Ethicon adopts its Wave 3 reply argument on this issue set forth in Section IX of Doc. 3024.

CONCLUSION

For the reasons set forth herein and in its prior briefing, Ethicon respectfully requests that the Court grant its Motion to Exclude the Testimony of Bruce Rosenzweig, M.D.

Respectfully Submitted,

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I hereby certify that on this day I electronically filed the foregoing document with the Clerk of the Court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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